

WHAT IS CLAIMED IS:

1 1. A method for the volumetric distribution of a pharmaceutical agent in
2 the tissue of a living vertebrate host, said method comprising:

3 positioning a needle through the wall of a target blood vessel so that an
4 aperture of the needle is positioned beyond an external elastic lamina (EEL) of the wall by a
5 distance not exceeding 5 mm; and

6 delivering an amount of the pharmaceutical agent from the aperture so that the
7 agent distributes both longitudinally and radially from the injection site.

1 2. A method as set in claim 1, wherein the agent distributes longitudinally
2 along the blood vessel over a distance of at least 1 cm and radially by a distance of at least 1
3 cm or within a time period no greater than 60 minutes.

1 3. A method as in claim 2, wherein the concentrations of agent at all
2 locations spaced at least 2 cm from the delivery site are at least 10% of the concentration at
3 the delivery site.

1 4. A method as in claim 1, wherein the agent distributes via the lymphatic
2 system surrounding the target.

1 5. A method as in claim 1, wherein the aperture of the needle is
2 positioned at a distance less than 5 mm beyond the EEL .

1 6. A method as in claim 5, wherein pharmaceutical agent comprises a
2 small molecule drug, a protein, or a gene.

1 7. A method as in claim 6, wherein the agent has a maximum dimension
2 of 200 nm or below.

1 8. A method as in claim 1, wherein the blood vessel is a coronary blood
2 vessel.

1 9. A method as in claim 6 , wherein the coronary blood vessel is an
2 artery.

- 1 10. A method as in claim 7, wherein the coronary artery is at risk of
2 hyperplasia.
- 1 11. A method as in claim 7, wherein the coronary artery has regions of
2 vulnerable plaque.
- 1 12. A method as in claim 1, wherein the patient is suffering from
2 congestive heart failure or a cardiac arrhythmia.
- 1 13. A method as in claim 1, wherein the blood vessel is a cerebral blood
2 vessel and the tissue is in the brain of the host.
- 1 14. A method as in claim 1, wherein the blood vessel is a hepatic blood
2 vessel and the tissue is in the liver of the host.
- 1 15. A method as in claim 1, wherein the agent is being delivered to treat a
2 neoplastic disease in the tissue.
- 1 16. A method as in claim 1, further comprising:
2 confirming that the aperture is positioned beyond the EEL before delivering
3 the amount of pharmaceutical agent.
- 1 17. An improved method for injecting a pharmaceutical agent into the
2 tissue of a living host using a needle positioned from a lumen of a blood vessel, wherein the
3 improvement comprises positioning the needle outwardly from the blood vessel lumen and
4 confirming that a delivery aperture of the needle has penetrated into tissue beyond an external
5 elastic lamina (EEL) of the blood vessel before injecting the pharmaceutical agent.
- 1 18. An improved method as in claim 17, wherein confirming comprises
2 injecting contrast media through the needle aperture and observing distribution of the media.
- 1 19. An improved method as in claim 17, wherein confirming comprises
2 monitoring injection pressure.
- 1 20. An improved method as in claim 17, wherein confirming comprises
2 monitoring temperature near the delivery aperture.

1 21. An improved method as in claim 17, wherein confirming comprises
2 monitoring pH near the delivery aperture.

1 22. An improved method as in claim 17, wherein confirming comprises
2 monitoring electrical impedance near the delivery aperture.

1 23. An improved method as in claim 17, wherein confirming comprises
2 monitoring insertion force while positioning the needle through the EEL.

1 24. A catheter comprising:
2 a catheter body;
3 a needle having an aperture and being deployable from the catheter body; and
4 means coupled to the needle for detecting when the aperture of the needle has
5 advanced beyond the external elastic lamina of the blood vessel.

1 25. A catheter as in claim 24, wherein the detecting means comprises a
2 temperature sensor attached to the needle near the aperture.

1 26. A catheter as in claim 24, wherein the detecting means comprises an
2 electrical impedance sensor attached to the needle near the aperture.

1 27. A catheter as in claim 24, wherein the detecting means comprises a pH
2 sensor attached to the needle near the aperture.

1 28. A catheter as in claim 24, wherein the detecting means comprises an
2 insertion force sensor coupled to the needle.

1 29. A kit for delivering a pharmaceutical agent to a patient suffering from
2 or at risk of vascular disease, said kit comprising:
3 a catheter having a needle which can be advanced from a blood vessel lumen
4 through a wall of the blood vessel to position an aperture of the needle beyond an external
5 elastic lamina (EEL) of the wall by a distance not exceeding 5 mm; and
6 instructions for use setting forth a method comprising:
7 positioning the needle through the wall of the target blood vessel so that the
8 aperture of the needle is positioned beyond the external elastic lamina (EEL) of the wall by a
9 distance not exceeding 5 mm; and

- 10 delivering an amount of the pharmaceutical agent from the aperture so that the
- 11 agent distributes both longitudinally and radially from the injection site.